conect 4children
COLLABORATIVE NETWORK FOR EUROPEAN CLINICAL TRIALS FOR CHILDREN

Paving the future for the treatment of paediatric diseases through a Pan-European Clinical Trials Network

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under Grant Agreement Nº777389. The Join Undertaking receives sup port from the European Union´s H2020 research and innovation programme and EFPIA

Vision & Mission

Better medicines for babies, children and young people through a pan-European clinical trial network.

c4c will use a coordinated approach to deliver high quality "regulatory grade" clinical trials in:

- Multiple countries
- Multiple sites
- All paediatric age groups

By supporting:

- Trial implementation using resources shared between studies
- Trial design through a combination of information about natural history, feasibility, appropriate innovation, and expert opinion
- Education and awareness within and beyond the network

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A pan-EU Paediatric Clinical Trial Network

A project under the EU Innovative Medicines Initiative (IMI)

- Ensure **efficacy, safety & quality** of health products
- **Reduce time** to clinical proof of concept
- Improve the current **drug development process**
- Develop **new therapies** for diseases with **high unmet need** & **limited market incentives**
- Allow **engagement** in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research
- Ensure the **voice of patients** is heard to safeguard better treatments for children

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Key objectives

More efficient trial implementation through the set-up of **national hubs** and qualified sites.

Business cases for **sustainability** beyond IMI funding

Input in clinical trial design and implementation from pilot **expert advisory groups** and other fora.

Identification of **Data standards and performance metrics.**

Educational programme for health professionals and awareness raising campaigns for the general public.

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Key features

- International network with **lean central coordination**
- A **single point of contact**
- **Efficient** implementation of trials
- **Consistent** procedures across sites
- **Strategic and operational** feasibility assessment
- **Involvement of experts** to develop innovative trial designs & methodology
- **Multi-KEY** stakeholder collaboration

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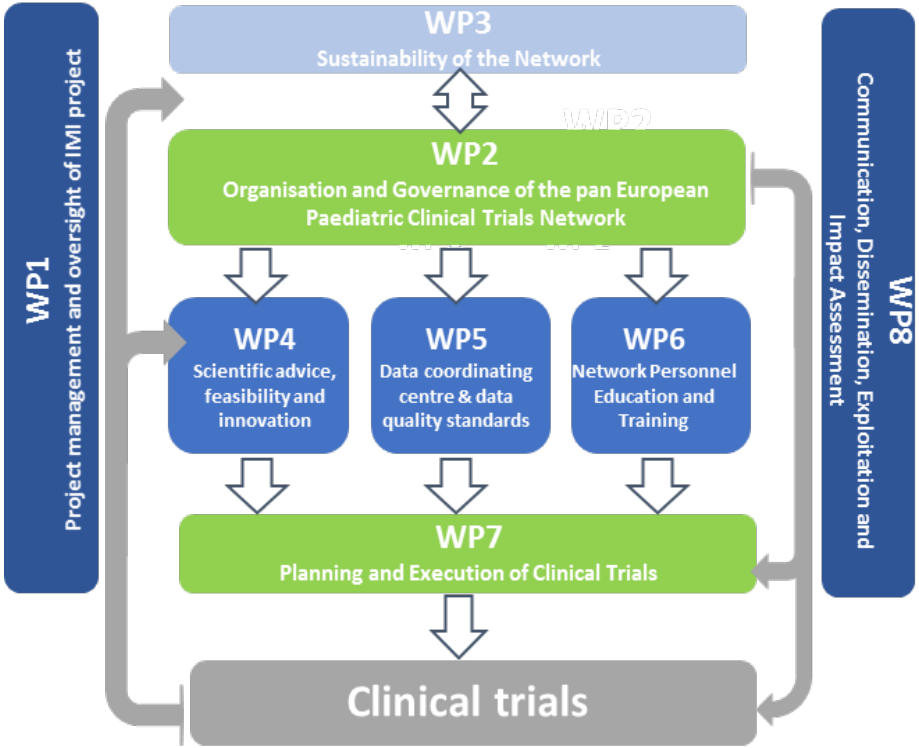
Implementation of the project plan



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Private-public partnership between Academia and Pharma

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Global Paediatric clinical trials networks

US

DCRI -GPN(Global Pediatric Network – Duke)

i-ACT

Canada

Kids CAN

Europe

c4c

PENTA-ID /PRINTO/CF/SIOPE/ECRIN…

Japan

Japanese Pediatric Network for Drug Development

Australia

Pediatric Trials Network of Australia (PTNA)

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The c4c national Hubs

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RECLIP – Spanish Pediatric Clinical Trials Network

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RECLIP – Spanish Pediatric Clinical Trials Network

National Institutions
AGENCIA ESPAÑOLA DEL MEDICAMENTO Y PRODUCTOS SANITARIOS
ASOCIACIÓN DE MEDICINA DE LA INDUSTRIA FARMACÉUTICA
ASOCIACIÓN EMPRESARIAL DE LA INDUSTRIA FARMACEUTICA
ASOCIACIÓN ESPAÑOLA DE PEDIATRÍA
International Institutions
Enpr-EMA, Red de Investigación Clínica Pediátrica EMA

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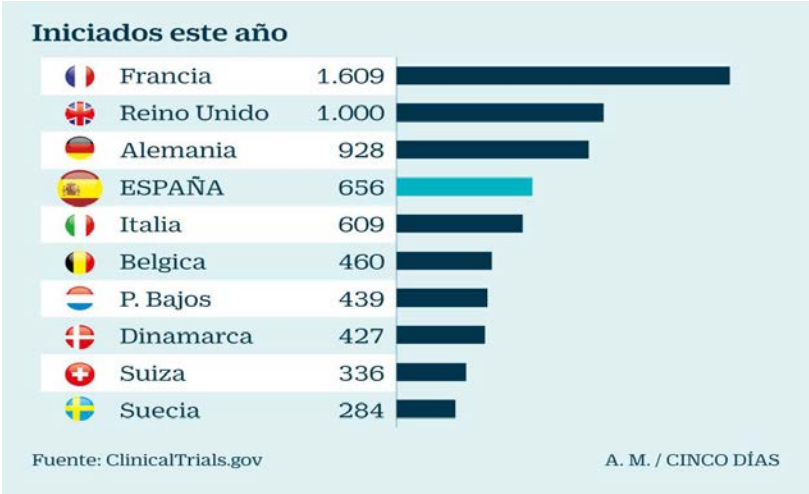
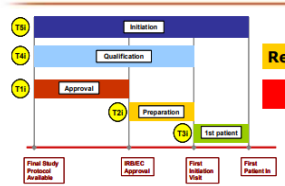
General overview of the European context





Se muestra el **puesto** que ocupa **España** dentro de cada etapa.

El número 1 es el país que menos tarda en esa etapa.

Source: Datos y Análisis 25ª Publicación BDMetrics 5-Nov-2018

Approval	Preparation	1st patient	Qualification	Initiation
1	1	1	1	1
2	2	2	2	2
3	3	3	3	3
4	4	4	4	4
5	5	5	5	5
6	6	6	6	6
7	7	7	7	7
8	8	8	8	8
9	9	9	9	9
10	10	10	10	10
11	11	11	11	11
12	12	12	12	12
13	13	13	13	13
14	14	14	14	14
15	15	15	15	15
16	16	16	16	16
17	17	17	17	17
18	18	18	18	18
19	19	19	19	19
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21	21	21	21	21
22	22	22	22	22
23	23	23	23	23
24	24	24	24	24
25	25	25	25	25
26	26	26	26	26
27	27	27	27	27
28	28	28	28	28
29	29	29	29	29
30				30
				31

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How c4c will be put to test

Proof-of-viability trials

- Industry sponsored
- Non-industry-sponsored

Selecting and comparing metrics about studies' start-up and conduct

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Expected long term impact of c4c

- **i** — **Access to new experimental therapies** for children in well-designed clinical trials
- **m** — **Better training** for research personnel and **improved trial readiness** at all participating sites
- **p** — **Improved efficiency** in executing trials (faster, cheaper)
- **a** — **Improved data quality** for labelling of next generation medicines for children
- **c** — Enhanced role of **clinicians and patient/parent advocacy groups** in planning and designing studies
- **t** — **Broadening the access** of academic medical centers and clinical faculty across Europe to new experimental therapies

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¡GRACIAS POR VUESTRA ATENCIÓN!

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